

EXHIBIT B

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 -----)
5 IN RE: ETHICON, INC. PELVIC) Master File
6 REPAIR SYSTEM PRODUCTS) No. 2:12-MD-02327
7 LIABILITY LITIGATION) MDL 2327
8)
9 THIS RELATES TO ALL WAVE 6)
10 AND SUBSEQUENT WAVE CASES) JOSEPH R. GOODWIN
11 AND PLAINTIFFS:) U.S. DISTRICT
12) JUDGE
13 Jerene Maxwell)
14 Case No. 2:13-cv-01703)
15)
16 Patricia Smith)
17 Case No. 2:12-cv-09857)
18 -----)

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21
22 --- Teleconference Deposition upon Oral
23 Examination of TERENCE J. COLGAN, M.D. called for
24 examination in the above titled action by the
25 Plaintiffs, by and through their attorneys,

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| Page 2 | Page 4 |
| 1 conducted in accordance with Rule 30 of the Federal | 1 |
| 2 Rules of Civil Procedure and the procedures set | 2 INDEX OF PROCEEDINGS |
| 3 forth in In Re: Ethicon Inc., Pelvic Repair System | 3 |
| 4 Products Liability Litigation, MDL No. 2327, taken | 4 WITNESS: TERENCE J. COLGAN, M.D. |
| 5 before me, the undersigned, Bonnie Lynn van der | 5 PAGE |
| 6 Meer, C.S.R. (Ontario), Certified Shorthand | 6 EXAMINATION BY MR. RESTAINO.....8 |
| 7 Reporter and Commissioner of Oaths within and for | 7 EXAMINATION BY MR. DAVIS.....156 |
| 8 the Province of Ontario, at the law offices of | 8 EXAMINATION BY MR. RESTAINO (CONT'D).....162 |
| 9 Blake, Cassels & Graydon LLP, 199 Bay Street | 9 ----- |
| 10 Suite 4000, Commerce Court West, Toronto, Ontario, | 10 |
| 11 Canada, M5L 1A9, on Thursday, the 21st day of | 11 ---[Reporter's note: The following indices of |
| 12 September, 2017, commencing at 8:59 a.m. (EST) and | 12 undertakings and refusals are provided for the |
| 13 concluding the same day. | 13 assistance of counsel and do not purport to be |
| 14 | 14 complete or binding on the parties herein.] |
| 15 | 15 |
| 16 | 16 INDEX OF UNDERTAKINGS |
| 17 | 17 The questions/requests refused are noted by U/T and |
| 18 | 18 appear on the following pages: 12:10, 15:2. |
| 19 | 19 ----- |
| 20 | 20 |
| 21 | 21 |
| 22 | 22 INDEX OF REFUSALS |
| 23 | 23 The questions/requests refused are noted by R/F and |
| 24 | 24 appear on the following pages: (None). |
| 25 | 25 ----- |
| Page 3 | Page 5 |
| 1 APPEARANCES: | 1 INDEX OF EXHIBITS |
| 2 (REPORTER'S NOTE: There were no remote attendees.) | 2 |
| 3 | 3 EXHIBIT NUMBER DESCRIPTION PAGE/LINE |
| 4 FOR PLAINTIFFS: | 4 1: Notice to Take Deposition of Dr. Terry |
| 5 RESTAINO LAW LLC | 5 Colgan with respect to Case 2:12-MD-02327 |
| 6 BY: JOHN M. RESTAINO JR., ESQ., DPM, JD, MPH | 6 on September 21, 2017, pages 2 to 9, |
| 7 1011 S. Josephine St. | 7 electronically filed on September 19, 2017 |
| 8 Denver, Colorado 80209 | 8 by D. Renée Baggett of Aylstock, Witkin.....10:18 |
| 9 Phone: 303-839-8000 | 9 2: A USB thumb drive containing case-related |
| 10 Fax: 720-221-0449 | 10 electronic documents connected to a key fob |
| 11 Email: JRestaino@Restainolawfirm.com | 11 labelled "General - Dr. Colgan"13:21 |
| 12 | 12 3: Academic Curriculum Vitae of Dr. Terence |
| 13 FOR DEFENDANTS, JOHNSON & JOHNSON | 13 (Terry) J. Colgan, dated November 14, 2016, pages |
| 14 AND ETHICON, INC.: | 14 1 to 60.....14:11 |
| 15 BUTLER SNOW LLP | 15 4: Document entitled Terence Colgan, General |
| 16 BY: PAUL N. DAVIS, ESQ. | 16 Reliance List in Addition to Materials |
| 17 1020 Highland Colony Parkway, Suite 1400 | 17 Referenced in Report, MDL Wave 6.....17:18 |
| 18 Ridgeland, Mississippi 39157 | 18 5: A printout of a web page pertaining to |
| 19 Phone: 601-948-5711 | 19 Terence Colgan, MD, FRCPC, from the website of |
| 20 Fax: 601-985-4500 | 20 University of Toronto Laboratory Medicine & |
| 21 Email: paul.davis@butlersnow.com | 21 Pathobiology Faculty Research Database.....30:19 |
| 22 | 22 6: Expert Report of Terence J. Colgan, MD, |
| 23 COURT REPORTER: Bonnie Lynn van der Meer, CSR | 23 dated June 19, 2017, with attached references, |
| 24 Commissioner of Oaths | 24 pages 1 to 25.....39:24 |
| 25 (Commission Expires August 4, 2019) | 25 7: A printout of the University of Toronto |

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| <p style="text-align: right;">Page 22</p> <p>1 pathology?</p> <p>2 A. I think if one isn't in an</p> <p>3 academic pathology environment and is restricted to</p> <p>4 clinical practice only, then it would be the</p> <p>5 diagnosis of disease through tissues and fluids.</p> <p>6 Q. And is your... (Clearing throat)</p> <p>7 Excuse me. I'm sorry.</p> <p>8 Is it your academic interest, as a</p> <p>9 pathologist, to look into the -- to gain insight</p> <p>10 into the etiology of disease?</p> <p>11 A. Yes, within the time allotted in</p> <p>12 my position.</p> <p>13 Q. What do you mean by that?</p> <p>14 A. I spend most of my time doing</p> <p>15 diagnosis through the examination of tissues.</p> <p>16 Q. Okay. So tissue that comes to you</p> <p>17 say, for example, from the Operating Room?</p> <p>18 A. That's right.</p> <p>19 Q. Okay. And in your role as a</p> <p>20 pathologist, do you seek to determine how the body</p> <p>21 responds to and repairs injury?</p> <p>22 A. On a daily basis, I don't seek to</p> <p>23 identify how the body responds to injury.</p> <p>24 Q. Okay.</p> <p>25 A. I use what is available in the</p> | <p style="text-align: right;">Page 24</p> <p>1 patients call me about cases, sometimes at the</p> <p>2 request of the gynecologist or treating surgeon,</p> <p>3 and so I do, on occasion, speak to patients and</p> <p>4 hear their concerns.</p> <p>5 Q. And while you are hearing of their</p> <p>6 concerns, are you listening both for the subjective</p> <p>7 complaints and listening for objective findings?</p> <p>8 A. This would usually be over the</p> <p>9 phone, so I think by your question, these would be</p> <p>10 qualified as subjective and not verified by</p> <p>11 objective examination.</p> <p>12 Q. I guess I was thinking along the</p> <p>13 lines of, if a patient called you up and said, 'I'm</p> <p>14 doing well after surgery, but I have a</p> <p>15 temperature,' and then you say, 'Well, what is your</p> <p>16 -- have you taken your temperature?'</p> <p>17 'Yes. It's 101.'</p> <p>18 The complaint of a temperature would be</p> <p>19 subjective. The reading of 101 would be objective.</p> <p>20 Would you agree?</p> <p>21 A. I agree.</p> <p>22 Q. And so that's why I was asking if,</p> <p>23 in your conversations, do you attempt to ascertain</p> <p>24 objective data from a patient?</p> <p>25 A. My conversations with patients are</p> |
| <p style="text-align: right;">Page 23</p> <p>1 published surgical pathology literature.</p> <p>2 Q. Okay. Now, are you a</p> <p>3 gynecologist?</p> <p>4 A. No, I am not.</p> <p>5 Q. Are you a uro-oncologist?</p> <p>6 A. No, I am not.</p> <p>7 Q. And are you a urogynecologist?</p> <p>8 A. No, I am not.</p> <p>9 Q. Okay. When was the last time you</p> <p>10 took a history from a living patient? And this</p> <p>11 could be one of those estimate questions. I don't</p> <p>12 need the day.</p> <p>13 A. I have been practicing pathology</p> <p>14 for over 25 years and during that time, I -- it has</p> <p>15 not been my role to interact directly with patients</p> <p>16 and to take clinical histories.</p> <p>17 Q. Okay. And if I was to ask you,</p> <p>18 when was the last time you performed a physical</p> <p>19 examination on a patient, would your answer be the</p> <p>20 same?</p> <p>21 A. Yes, it would.</p> <p>22 Q. If I was to ask you, when was the</p> <p>23 last time you listened to subjective complaints of</p> <p>24 a patient, would your answer be the same?</p> <p>25 A. No. I do, on occasion, have</p> | <p style="text-align: right;">Page 25</p> <p>1 on occasion and are very brief.</p> <p>2 If, in fact, the patient had a concern</p> <p>3 of that magnitude, I would direct them to their</p> <p>4 treating surgeon.</p> <p>5 Q. Okay. Fair enough.</p> <p>6 Prior to reviewing any pathological</p> <p>7 material that may be sent to you, when is the last</p> <p>8 time that you have listened to the complaints of a</p> <p>9 woman who was having mesh - and for purposes of</p> <p>10 today's deposition, we'll be talking about the</p> <p>11 mid-urethral sling and the other mesh that is used</p> <p>12 for stress incontinence.</p> <p>13 So when is the last time you listened</p> <p>14 to complaints of a patient pre surgical excision?</p> <p>15 A. I cannot recall a time when I had,</p> <p>16 in fact, spoken to a patient pre surgical excision.</p> <p>17 Q. Okay. Now, you have examined mesh</p> <p>18 that had been removed from women?</p> <p>19 A. Yes, I have.</p> <p>20 Q. Can you estimate for us</p> <p>21 approximately how many times you have reviewed --</p> <p>22 you have examined mesh?</p> <p>23 A. Over the 25-plus years of my</p> <p>24 practice, there would be dozens of times.</p> <p>25 Q. Okay. Have you had occasions in</p> |

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| <p style="text-align: right;">Page 26</p> <p>1 the past where a surgeon sends to you, from the 2 Operating Room, polypropylene sutures that have 3 been removed because of a painful suture reaction? 4 A. I cannot recall a time when we've 5 had a -- such a specimen. 6 Q. Have you heard of the term 7 "spinning suture"? 8 A. No, I have not. 9 Q. Perhaps there's another way of 10 describing it. When a -- when the body forms a 11 granuloma around an irritating suture and begins to 12 try to move it out. 13 And the surgeon will see a nodule, take 14 it out, and therein is a piece of suture. 15 Have you encountered that? 16 A. I do not recall seeing such a 17 specimen, but I would wonder if such a specimen 18 would necessarily be submitted to the pathology lab 19 if it consisted of a single suture thread removed, 20 say, in the Emergency Room or Outpatient Clinic. 21 There are guidelines in our province 22 for which specimens do and do not have to be 23 submitted to Pathology. 24 Q. So if I understand you correctly, 25 if a surgeon removes a simple piece of suture, that</p> | <p style="text-align: right;">Page 28</p> <p>1 Laboratory Medicine and Pathobiology at the 2 university. Is that correct? 3 A. The University of Toronto is an 4 umbrella academic organization which embraces 5 several to multiple hospitals across Toronto. 6 So my clinical appointment is at the 7 Sinai Health System or Mount Sinai Hospital where I 8 conduct my clinical practice. 9 Q. So it's one institution with 10 umbrella hospitals. Is that correct? 11 A. It's the umbrella university over 12 many different hospitals. 13 Q. Okay. 14 A. And my clinical practice would be 15 restricted to the one hospital system. 16 Q. Okay. Now, a colleague at the 17 University of Toronto in the Department of 18 Pathology is Dr. Vladimir - forgive me if I'm not 19 going to pronounce his last name correctly. Is it 20 "Iakolev" (ph)? 21 MR. DAVIS: "Iakolev" (ph). 22 "Iakovlev". 23 MR. RESTAINO: "Iakolev"? 24 MR. DAVIS: "Iakovlev". 25 BY MR. RAPHAEL:</p> |
| <p style="text-align: right;">Page 27</p> <p>1 may not be sent to Pathology. 2 But if he excised a granuloma with the 3 suture inside, would you expect that tissue to be 4 sent to Pathology? 5 A. If there has been a biopsy, as you 6 -- I think you're describing, yes, it would be sent 7 to Pathology. 8 Q. And have you had an opportunity to 9 examine such material and see a suture within it? 10 A. I can't recall a specimen which 11 has been removed purely for the suture. 12 We do see suture in specimens which 13 have been subjected to previous surgeries. So for 14 example, ovarian cystectomy in a remote time 15 followed up by an excision of the ovary and 16 fallopian tube of the same side. 17 Q. Okay. In such a situation, have 18 you had the opportunity to see an allergic or 19 foreign body reaction to the suture material? 20 A. Yes, I have -- I've seen a foreign 21 body reaction to suture material. 22 I wouldn't know how to identify an 23 allergic reaction. 24 Q. Okay. So now, I believe you 25 shared with us that you are in the Department of</p> | <p style="text-align: right;">Page 29</p> <p>1 Q. "Iakovlev". Okay. Yeah. 2 It's spelled I-a-k-o-v-I-e-v. 3 MR. DAVIS: I have deposed him a number 4 of times and that's about as best I can say it is 5 "Iakovlev". 6 MR. RESTAINO: "Iakovlev". Okay. We 7 will do our best. 8 BY MR. RESTAINO: 9 Q. Do you know this physician? 10 A. I only know him as a distant 11 colleague. He did train through the university 12 program and moved through our hospital years ago. 13 But he is based at St. Michael's 14 Hospital and I do not work with him or interact 15 with him at all. 16 Q. But it's fair to say he is in the 17 same institution, the University of Toronto, and in 18 the Department of Laboratory Medicine in 19 Pathobiology; correct? 20 A. Correct. 21 Q. Okay. 22 A. You should understand that the 23 university department has over 300 appointees. 24 Q. I understand. 25 Have you ever collaborated with him on</p> |

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| <p style="text-align: right;">Page 38</p> <p>1 Q. Okay. Have you ever received 2 funding from Ethicon or any other manufacturer of 3 mesh, whether abdominal or pelvic, to conduct 4 research on?</p> <p>5 A. No, I have not.</p> <p>6 Q. From looking at your CV, you have 7 overseen the responsibilities of various visiting 8 scholars and fellows to Mount Sinai Hospital. Is 9 that correct?</p> <p>10 A. This is correct.</p> <p>11 Q. And have you ever overseen a 12 visiting scholar or fellow conducting research into 13 vaginal mesh?</p> <p>14 A. No, I have not.</p> <p>15 Q. Or abdominal mesh?</p> <p>16 A. No, I have not.</p> <p>17 Q. Looking at your 2016 CV, I counted 18 that there were 152 articles, refereed or 19 peer-reviewed articles.</p> <p>20 Is it your testimony today that the 21 latest or most current CV would contain more than 22 that 152.</p> <p>23 A. Yes. It would probably be closer 24 to 160.</p> <p>25 Q. Okay. Any of those, refereed or</p> | <p style="text-align: right;">Page 40</p> <p>1 attached references, pages 1 to 25.</p> <p>2 BY MR. RESTAINO:</p> <p>3 Q. Dr. Colgan, do you recognize this 4 document?</p> <p>5 A. Yes, I do.</p> <p>6 Q. And on page 21 of the document 7 it's signed on June 19, 2017.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. That's your signature?</p> <p>11 A. That is my signature.</p> <p>12 Q. And above that, it indicates that 13 you haven't given any testimony in the last four 14 years.</p> <p>15 Is that still accurate?</p> <p>16 A. This is still accurate.</p> <p>17 Q. And above that, it states that 18 your billing rate is \$500 an hour.</p> <p>19 Is that still accurate?</p> <p>20 A. That is still accurate.</p> <p>21 Q. Without being provided with any 22 invoices, this will be one of those estimate 23 questions.</p> <p>24 Let me ask you this first: When were 25 you first approached by anyone to provide an expert</p> |
| <p style="text-align: right;">Page 39</p> <p>1 peer-reviewed articles published in the 2 peer-reviewed medicine deal with vaginal or -- or 3 abdominal mesh?</p> <p>4 A. No, they do not.</p> <p>5 Q. Now, again looking at papers that 6 have been presented to learned societies in your 7 CV, have you ever presented any papers to a learned 8 society on abdominal or vaginal mesh?</p> <p>9 A. No, I have not.</p> <p>10 Q. Looking at Dr. Iakovlev's CV, I 11 noticed that he lists a number of lectures, 12 workshops and visiting professorships where he has 13 lectured on the pathology associated with mesh.</p> <p>14 To the best of your recollection, have 15 you ever attended any of those lectures?</p> <p>16 A. To my best of my recollection, no, 17 I have not attended any of those workshops.</p> <p>18 Q. Okay.</p> <p>19 MR. RESTAINO: I'm now going to ask the 20 court reporter to mark as Number 6 the expert 21 report that I have been provided with that is 22 authored by yourself.</p> <p>23 --- (Discussion off the record.)</p> <p>24 --- EXHIBIT NO. 6: Expert Report of 25 Terence J. Colgan, MD, dated June 19, 2017, with</p> | <p style="text-align: right;">Page 41</p> <p>1 -- expert opinions regarding vaginal mesh and 2 pathology?</p> <p>3 A. It was late in 2016.</p> <p>4 Q. And who was it that contacted you 5 at that time?</p> <p>6 A. It was Mr. Andy Snowden.</p> <p>7 Q. And were you asked to do anything 8 at that time for Mr. -- well, let me ask you this: 9 Was Mr. Snowden a representative of Ethicon?</p> <p>10 A. He is a lawyer with Snow Butler.</p> <p>11 Q. Okay.</p> <p>12 A. At that time, I did not know who 13 he was representing.</p> <p>14 Q. Okay.</p> <p>15 MR. DAVIS: It's actually Butler Snow, 16 but that doesn't matter.</p> <p>17 THE WITNESS: Sorry.</p> <p>18 MR. DAVIS: That's all right.</p> <p>19 BY MR. RESTAINO:</p> <p>20 Q. And at that time, did you hold 21 yourself out to be an expert in pathology 22 associated with vaginal mesh?</p> <p>23 A. I did not hold myself out to be an 24 expert in vaginal mesh.</p> <p>25 He had called me because I have been</p> |

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| <p style="text-align: right;">Page 42</p> <p>1 active and I would like to think somewhat prominent</p> <p>2 in the gynecologic pathology community in North</p> <p>3 America.</p> <p>4 Q. Okay. Do you have any expertise</p> <p>5 in the pathology associated with mesh utilized for</p> <p>6 herniorrhaphy or abdominal repairs?</p> <p>7 A. No, I do not.</p> <p>8 Q. Okay. If, tomorrow, when you are</p> <p>9 in your real job, a general surgeon removes mesh</p> <p>10 from the abdomen, would that be something that</p> <p>11 would be sent to you or would that go to another</p> <p>12 pathologist in your department?</p> <p>13 A. Until very recently, it would have</p> <p>14 come to me.</p> <p>15 Our hospital has recently adopted a</p> <p>16 subspecialty practice model, so abdominal material</p> <p>17 would move to another group of pathologists.</p> <p>18 Q. Okay.</p> <p>19 If you look at page 3 -- first, on the</p> <p>20 expert report, did you write this yourself?</p> <p>21 A. I did.</p> <p>22 Q. Is there any language in there</p> <p>23 that was provided to you by anyone else?</p> <p>24 A. I had general discussions with</p> <p>25 Mr. Snowden, but no, this is my work.</p> | <p style="text-align: right;">Page 44</p> <p>1 A. So, for example, Blaustein's is a</p> <p>2 very standard text and it's called Blaustein's</p> <p>3 Pathology of the Female Genital Tract, as I recall.</p> <p>4 Q. And what edition of Blaustein's do</p> <p>5 you have?</p> <p>6 A. Well, I have several texts. I</p> <p>7 can't recall the number of every edition.</p> <p>8 Q. Okay. Fair enough.</p> <p>9 Would you agree that chapters in</p> <p>10 medical textbooks, unlike articles in medical</p> <p>11 journals, are not peer reviewed?</p> <p>12 A. This is a difficult question.</p> <p>13 I think there are journals which</p> <p>14 purport to be peer reviewed, but in fact have lax</p> <p>15 standards and oversights.</p> <p>16 Similarly, a good -- or in distinction,</p> <p>17 a good text with a good editor can be considered to</p> <p>18 be peer-reviewed because the editor had a rigorous</p> <p>19 examination of each and every one of his chapters</p> <p>20 author's product.</p> <p>21 Q. Okay. Who should do that rigorous</p> <p>22 examination of each chapter?</p> <p>23 A. It would be the editor of the --</p> <p>24 of the textbook.</p> <p>25 So, for example, Blaustein's Pathology</p> |
| <p style="text-align: right;">Page 43</p> <p>1 Q. Okay. Not infrequently, in</p> <p>2 academia, an author may utilize a resident, a</p> <p>3 fellow, a research assistant to help them research</p> <p>4 the topic and perhaps provide some outline work.</p> <p>5 Did you utilize anyone like that in</p> <p>6 writing this paper?</p> <p>7 A. No. I did not use any other</p> <p>8 writer or assistant, fellow or editorial assistant.</p> <p>9 It is my work and I -- using references</p> <p>10 and -- that I studied and general texts, and my own</p> <p>11 25 years experience.</p> <p>12 Q. Now, you mentioned the word</p> <p>13 "references".</p> <p>14 In preparation for developing your</p> <p>15 expert opinions that you will share today and in</p> <p>16 writing your report, did you conduct any search of</p> <p>17 medical literature through any database; for</p> <p>18 example, PubMed?</p> <p>19 A. I did conduct research. I did use</p> <p>20 PubMed. I did use my generalized -- or my general</p> <p>21 texts, as well.</p> <p>22 Q. What do you mean by "general</p> <p>23 texts"?</p> <p>24 A. Gynecologic pathology texts.</p> <p>25 Q. So --</p> | <p style="text-align: right;">Page 45</p> <p>1 may have 30 or 40 different chapter authors, but</p> <p>2 there's only three editors-in-chief. Their name</p> <p>3 goes on the front.</p> <p>4 Q. So of those 30 or so authors, if</p> <p>5 each had their own chapter - so let's just assume</p> <p>6 for a moment there's 30 chapters - would you expect</p> <p>7 those three editors to have that degree of</p> <p>8 expertise to peer-review the subject matter in all</p> <p>9 30 areas?</p> <p>10 A. The editors contribute in two</p> <p>11 ways. One is in substance and, as you suggest, the</p> <p>12 chapter authors may have greater knowledge of that</p> <p>13 particular area.</p> <p>14 But the second duty an editor has is to</p> <p>15 look at the rationale of arguments; has the</p> <p>16 scientific proof been made, which is important to</p> <p>17 the overall success of the text.</p> <p>18 Q. Okay. Would you agree that peer</p> <p>19 review is an important part of medical publication,</p> <p>20 whether it's in textbooks and/or medical journals?</p> <p>21 A. The success of peer review has</p> <p>22 come under scrutiny in the last ten years with the</p> <p>23 rise of electronic publishing.</p> <p>24 I think, years ago, scientists were</p> <p>25 wedded to the concept that peer review was</p> |

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| <p style="text-align: right;">Page 46</p> <p>1 essential to a scientific article and provided good 2 scientific evidence.</p> <p>3 What we are seeing now, though, with 4 the proliferation of journals and of electronic 5 media, is that quality of peer review can be very 6 spotty and, in fact, the best outcome or the best 7 way to judge the success and veracity of a paper is 8 its influence down the road. Is it used? Are its 9 findings duplicated or not?</p> <p>10 Q. If you would turn in your expert 11 report to page 3. The fourth line down on the 12 right, you write:</p> <p>13 "I see over 5,000 cases per 14 annum."</p> <p>15 Do you see that, sir?</p> <p>16 A. Actually, I must be on the wrong 17 page.</p> <p>18 Q. Page 3.</p> <p>19 A. Yeah. Sorry.</p> <p>20 As chance would have it, I'm missing 21 page 3.</p> <p>22 MR. DAVIS: You know what? The copy 23 you gave me has two page 3's. It may have been -- 24 it may have been that my copy --</p> <p>25 MR. RESTAINO: That was my stapling</p> | <p style="text-align: right;">Page 48</p> <p>1 Pathology at the University of Toronto in toto?</p> <p>2 A. I know of no database that would 3 tell you that number.</p> <p>4 Q. Okay. Now still on page 3 which 5 you don't have and Paul has two copies of, 6 approximately at the middle of the page, you write 7 that, as you discuss having contributed to over 150 8 articles:</p> <p>9 "Two of the papers examine the 10 inflammatory and healing reactions 11 in the gynecologic tract following 12 embolic therapy and hysteroscopic 13 surgery." [As read.]</p> <p>14 With references 1 and 2. Do you recall 15 that?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Why did you include those 18 references in your report on the pathology 19 associated with mesh?</p> <p>20 A. I thought they were germane 21 because there are shared similarities in the 22 inflammatory reaction to post-embolic therapy and 23 to hysteroscopic surgery; that is, they elicit a 24 macrophage and foreign body giant cell reaction, as 25 one can see in mesh or one almost ubiquitously sees</p> |
| <p style="text-align: right;">Page 47</p> <p>1 last night.</p> <p>2 MR. DAVIS: Yeah. That's all right.</p> <p>3 MR. RESTAINO: My apologies.</p> <p>4 THE WITNESS: Yes. There were five 5 thou- -- yes.</p> <p>6 BY MR. RESTAINO:</p> <p>7 Q. And I believe I have already asked 8 you this. Forgive me.</p> <p>9 Approximately, of those 5,000, can you 10 estimate how many of them involved mesh?</p> <p>11 A. It would be less than 1 per 12 percent.</p> <p>13 Q. Okay. And are there other members 14 of the Department of Laboratory Medicine and 15 Pathobiology at the University of Toronto that also 16 see mesh, vaginal mesh that had been excised from 17 women?</p> <p>18 A. There are active women's programs 19 and gynecologic divisions in most of the university 20 hospitals and I wouldn't be surprised if some, 21 perhaps many of them do excise mesh and these 22 specimens would be submitted to the hospital's 23 pathology department.</p> <p>24 Q. Okay. Do you have an estimate of 25 how many mesh are submitted to the Department of</p> | <p style="text-align: right;">Page 49</p> <p>1 in excised mesh specimens.</p> <p>2 Q. For the record and for whoever 3 else may be reviewing this transcript, first can 4 you define for us, when utilizing the term 5 "embolic", and the actual title of the article is 6 Pathologic Features of Uteri in Leiomyomas, 7 l-e-i-o-m-y-o-m-a-s, Following Uterine Artery 8 Embolization For Leiomyomas.</p> <p>9 What aspect of embolism would initiate 10 a macrophage reaction?</p> <p>11 A. Uterine artery -- arterial 12 embolization is a technique that radiologists have 13 developed where, after catheterization, material is 14 injected into the uterine arteries in order to, if 15 you will, starve the uterine leiomyomas of blood 16 supply, inducing shrinkage and avoiding surgery -- 17 any surgery, which would usually have been the 18 normal treatment.</p> <p>19 So embolization is an attempt to treat 20 uterine fibroids or leiomyomas and avoid major 21 surgery.</p> <p>22 Our study was looking at the 23 inflammatory response to that embolic material 24 within the uterine myometrium and adjacent tissues.</p> <p>25 It was of interest to surgical</p> |

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| <p style="text-align: right;">Page 54</p> <p>1 "...asked to review medical 2 literature, Dr. Iakovlev's research 3 and his written report in the matter 4 of allegations regarding possible 5 effects of the placement of 6 mid-urethral mesh slings in the 7 treatment of urinary stress 8 incontinence." [As read.] 9 Did I read that correctly, sir? 10 A. Sorry. I wasn't following with my 11 eye. I was listening to you. 12 Q. Okay. Who asked you to conduct a 13 review of the medical literature, Dr. Iakovlev's 14 research, and his written report? 15 A. Mr. Andy Snowden. 16 Q. And did that occur back in 2016 17 when you first met? 18 A. It occurred throughout the first 19 half of 2017. 20 Q. Okay. And as we had mentioned, 21 Dr. Iakovlev is a colleague of yours in the 22 University of Toronto Department of Laboratory 23 Medicines and Pathobiology; correct? 24 A. Correct. 25 MR. RESTAINO: I will go ahead and ask</p> | <p style="text-align: right;">Page 56</p> <p>1 A. We are peer pathologists, but 2 clearly he has interests of a different nature than 3 I do. 4 Q. Okay. Now, his paper was 5 published in the Journal of Biomedical Research 6 Part B Applied Biomaterials, and this was in 7 February of 2017. 8 Did you review this paper when it was 9 published? 10 A. No, I did not review -- I read it 11 after it was published. 12 Q. Okay. 13 A. When you say "review", I think of 14 prior to publication. 15 Q. And let me strike that. I 16 misspoke. 17 Did you read the paper when it was 18 published? 19 A. I had read the paper. 20 Q. Okay. And you read it at the time 21 it came out, approximately? 22 A. I read it earlier this year, so 23 yes, fairly soon after it appeared. 24 Q. Okay. Now, for purposes of your 25 expert report, you now, as a peer, have reviewed</p> |
| <p style="text-align: right;">Page 55</p> <p>1 the court reporter to mark his web page as Number 2 7, I think. 3 THE COURT REPORTER: Yes. 4 ---EXHIBIT NO. 7: A printout of the 5 University of Toronto Laboratory Medicine & 6 Pathobiology faculty web page pertaining to Dr. 7 Vladimir Iakovlev. 8 BY MR. RESTAINO: 9 Q. And again, I asked you, do you 10 know Dr. Iakovlev on a personal basis? 11 A. I do not know him on a personal 12 basis. 13 Q. Okay. 14 Now, one of the materials that you were 15 asked to review is a paper that is -- that was 16 co-authored by Dr. Iakovlev, titled Degradation of 17 polypropylene in vivo: A microscopic analysis of 18 meshes explanted from patients. 19 Is that correct? 20 A. That is correct. 21 Q. And did you, in fact, review that 22 for purposes of your expert report? 23 A. I did. 24 Q. And do you consider yourself a 25 peer of Dr. Iakovlev in this area?</p> | <p style="text-align: right;">Page 57</p> <p>1 this paper and his expert report; correct? 2 A. Correct. 3 Q. Are you a peer reviewer for the 4 Journal of Biomedical Research, Part B, Applied 5 Materials? 6 A. I am not. 7 Q. Have you ever been? 8 A. No. 9 Q. Okay. Now, in your role as both a 10 peer reviewer for the journals that you do conduct 11 peer review and have conducted peer review and in 12 your role of -- in your role as an associate 13 editor, you understand that there are certain 14 guidelines by which peer reviewers are selected; 15 correct? 16 A. Yes, I do. 17 Q. Do you understand that as a member 18 of the same institution, you would not be selected 19 to peer review this paper by Dr. Iakovlev because 20 of the appearance of conflict of interest? 21 A. Not at all. 22 University of Toronto is such a large 23 institution, it wouldn't be unusual for me to 24 review a paper from another hospital-- 25 Q. Have you ever --</p> |

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| <p style="text-align: right;">Page 58</p> <p>1 A. --in my area.</p> <p>2 Q. Have you ever been asked to be a</p> <p>3 peer reviewer for a colleague in the institution of</p> <p>4 the University of Toronto?</p> <p>5 A. I can't recall a specific</p> <p>6 instance, but I'm sure over my 20-plus years, I</p> <p>7 have.</p> <p>8 The University of Toronto is a very</p> <p>9 large research institution. Having or serving on a</p> <p>10 few journals, I would expect, over the years, I</p> <p>11 would have reviewed articles by colleagues with</p> <p>12 appointments at the University of Toronto.</p> <p>13 Q. Would you agree that you would not</p> <p>14 be asked to be a peer reviewer by any journal, to</p> <p>15 peer review a paper by a fellow department member?</p> <p>16 A. It would -- it's customary not to</p> <p>17 use somebody at the very same institution, so I</p> <p>18 would not be asked, in all likelihood, to review</p> <p>19 somebody at the Mount Sinai.</p> <p>20 But it would not be unusual if the</p> <p>21 paper came in from Sunnybrook Hospital, which is</p> <p>22 distant, but still under the umbrella of University</p> <p>23 of Toronto, to be asked to review a paper there.</p> <p>24 Q. Forgive me. I think your answer</p> <p>25 is a little different from what I was asking.</p> | <p style="text-align: right;">Page 60</p> <p>1 It would be acceptable and it may occur</p> <p>2 to review a paper from another institution within</p> <p>3 the University of Toronto system.</p> <p>4 BY MR. RESTAINO:</p> <p>5 Q. And would your answer be the same</p> <p>6 for the same department within an institution?</p> <p>7 MR. DAVIS: Object to the form.</p> <p>8 THE WITNESS: If what you're asking is,</p> <p>9 would it be acceptable to review a paper from a</p> <p>10 pathology department at Sunnybrook while I was</p> <p>11 based at the Mount Sinai, that may occur and is</p> <p>12 acceptable.</p> <p>13 MR. RESTAINO: I'm going to ask the</p> <p>14 court reporter to mark next a paper published by</p> <p>15 Human and Health Services Government, titled Ethics</p> <p>16 of Peer Review: A Guide for Manuscript Reviewers,</p> <p>17 and we'll make this Number 8.</p> <p>18 ---EXHIBIT NO. 8: A paper published by</p> <p>19 Human and Health Services Government, titled Ethics</p> <p>20 of Peer Review: A Guide for Manuscript Reviewers.</p> <p>21 BY MR. RESTAINO:</p> <p>22 Q. It's a large document, so I've had</p> <p>23 the court reporter mark the entire document.</p> <p>24 To save trees, I've just made copies of</p> <p>25 the pertinent areas. And if you would slide down,</p> |
| <p style="text-align: right;">Page 59</p> <p>1 Aside from the hospital itself, would</p> <p>2 you agree that you would not be asked to be a peer</p> <p>3 reviewer for anyone within the Department of</p> <p>4 Laboratory Medicine and Pathobiology of the</p> <p>5 University of Toronto?</p> <p>6 A. Could you clarify the question,</p> <p>7 please?</p> <p>8 Q. As we established and as the pages</p> <p>9 that I printed out establish, you and Dr. Iakovlev</p> <p>10 are both members of the Department of Pathology at</p> <p>11 University of Toronto; correct?</p> <p>12 A. Correct.</p> <p>13 Q. Would you agree that, (1), as an</p> <p>14 associate editor when you select peer reviewers,</p> <p>15 and, (2), when you're a peer reviewer yourself, you</p> <p>16 would not be asked to peer review a paper by a</p> <p>17 member in the same institution, let alone</p> <p>18 department, because of actual or apparent conflict</p> <p>19 of interest?</p> <p>20 MR. DAVIS: Object to the form and, I</p> <p>21 believe, asked and answered.</p> <p>22 But you can answer it.</p> <p>23 THE WITNESS: As I mentioned, it would</p> <p>24 be extremely unusual or inappropriate to be asked</p> <p>25 to review a paper of the same hospital institution.</p> | <p style="text-align: right;">Page 61</p> <p>1 if you could see, on page 5, which I believe I've</p> <p>2 highlighted under "Real or apparent conflicts of</p> <p>3 interest", I have highlighted that:</p> <p>4 "Most journals have policies</p> <p>5 that require that potential</p> <p>6 reviewers recuse themselves from</p> <p>7 reviewing manuscripts if they have</p> <p>8 real or apparent conflict of</p> <p>9 interest that might compromise the</p> <p>10 objectivity of the report or that</p> <p>11 might appear to compromise its</p> <p>12 objectivity." [As read.]</p> <p>13 Did I read that correctly?</p> <p>14 A. Mm-hmm.</p> <p>15 ---[Court reporter appeals.]</p> <p>16 MR. DAVIS: Be sure to say --</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. RESTAINO:</p> <p>19 Q. And then, if you would turn to</p> <p>20 page 9 of the document --</p> <p>21 MR. DAVIS: We don't have page 9.</p> <p>22 Do you have page 9?</p> <p>23 THE WITNESS: No.</p> <p>24 MR. RESTAINO: No? Oh. I'm sorry.</p> <p>25 Forgive me. I got ahead of myself.</p> |

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| <p style="text-align: right;">Page 66</p> <p>1 Did I read that correctly?</p> <p>2 A. Yes, you did.</p> <p>3 Q. And once again, we have</p> <p>4 established that not only are you in the same</p> <p>5 institution, the University of Toronto, but both</p> <p>6 you and Dr. Iakovlev are in the same Department of</p> <p>7 Pathology; correct?</p> <p>8 MR. DAVIS: Object to the form.</p> <p>9 THE WITNESS: Yes. I have said that we</p> <p>10 are in the same university and, once again, I will</p> <p>11 come back to the issue of what is an institution</p> <p>12 under concern, whether it's a hospital, the</p> <p>13 university or even a wider institution than that.</p> <p>14 I will also note that it says</p> <p>15 disclosure doesn't necessarily exclude the review.</p> <p>16 It should be disclosed.</p> <p>17 MR. RESTAINO: Okay. Why don't we go</p> <p>18 ahead and take our first hourly break.</p> <p>19 ---Recess at 10:09 a.m.</p> <p>20 ---On resuming at 10:17 a.m.</p> <p>21 MR. RESTAINO: I'm going to go ahead,</p> <p>22 then, and we've been talking a little bit about</p> <p>23 Dr. Iakovlev's paper, so I will go ahead and have</p> <p>24 Madam Court Reporter mark as 10 the actual paper</p> <p>25 itself for you.</p> | <p style="text-align: right;">Page 68</p> <p>1 Q. Okay.</p> <p>2 A. --after our discussions of late</p> <p>3 2016.</p> <p>4 Q. Okay. And once you read the</p> <p>5 paper, did you have criticisms of the methodology</p> <p>6 and/or conclusions in the paper?</p> <p>7 A. I did.</p> <p>8 Q. And at that time, did you attempt</p> <p>9 to contact the member of your department,</p> <p>10 Dr. Iakovlev, and discuss your criticisms?</p> <p>11 A. I did not.</p> <p>12 Q. Is there a reason why not?</p> <p>13 A. It was for two reasons at least.</p> <p>14 (1), it's not my custom to contact</p> <p>15 colleagues if I disagree with their paper.</p> <p>16 And (2) is, it was a published paper</p> <p>17 and it would be unlikely to come to any useful</p> <p>18 conclusion, short of retracting the entire article.</p> <p>19 Q. And is it your understanding that</p> <p>20 being published in the Journal of Biomedical</p> <p>21 Materials Research Part B: Applied Biomaterials,</p> <p>22 it is a peer-reviewed paper?</p> <p>23 A. I would expect it to be. I'm not</p> <p>24 familiar with its editorial board.</p> <p>25 Q. In August of 2015, Richard Hegele,</p> |
| <p style="text-align: right;">Page 67</p> <p>1 ---EXHIBIT NO. 10: A paper co-authored</p> <p>2 by Dr. Iakovlev, titled Degradation of</p> <p>3 polypropylene in vivo: A microscopic analysis of</p> <p>4 meshes explanted from patients, published in</p> <p>5 Journal of Biomedical Materials Research, February</p> <p>6 2017, Volume 105B, Issue 2.</p> <p>7 BY MR. RESTAINO:</p> <p>8 Q. Okay. Now, Dr. Colgan, I believe</p> <p>9 you testified that you read this paper after its</p> <p>10 publication.</p> <p>11 Is that correct?</p> <p>12 A. I read it after its electronic</p> <p>13 publication, yes.</p> <p>14 Q. And the electronic publication was</p> <p>15 in August of 2015?</p> <p>16 A. Yes.</p> <p>17 Q. And when you read this paper --</p> <p>18 well, with it being published in the Journal of</p> <p>19 Biomedical Materials Research, do you subscribe to</p> <p>20 this journal?</p> <p>21 A. I do not.</p> <p>22 Q. And why did you read this paper</p> <p>23 when it came out online or electronically in 2015?</p> <p>24 A. It was brought to my attention by</p> <p>25 Andrew Snowden--</p> | <p style="text-align: right;">Page 69</p> <p>1 H-e-g-e-l-e, MD, was the Chair of the University of</p> <p>2 Toronto Department of Pathology.</p> <p>3 Is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. Did you bring your criticisms of</p> <p>6 this paper to your department chair, indicating</p> <p>7 that a member of the department had published</p> <p>8 something that you disagreed with?</p> <p>9 A. No, I did not.</p> <p>10 Q. And currently, it's Avrum,</p> <p>11 A-v-r-u-m G-o-t-l-i-e-b, Gotlieb is...?</p> <p>12 A. Actually, he has stepped down.</p> <p>13 There's a new chair now. Her name is</p> <p>14 Rita Kandel, K-a-n-d-e-l. She took up her position</p> <p>15 as of April 1st, I believe it was.</p> <p>16 Q. With the current chair and/or the</p> <p>17 interim chair, Dr. Gotlieb, have you ever</p> <p>18 approached them with your criticisms of</p> <p>19 Dr. Iakovlev's paper?</p> <p>20 A. I did not.</p> <p>21 Q. When it came out, did you --</p> <p>22 A. Can I elaborate on that answer?</p> <p>23 Q. Of course.</p> <p>24 A. There is a university and</p> <p>25 departmental promotions and appointments committee</p> |

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| <p style="text-align: right;">Page 70</p> <p>1 whose duty it is to review the academic performance 2 of individuals. 3 It is -- I cannot think of an example 4 where an individual faculty member brought to the 5 departmental chair's attention an individual paper 6 as a criticism or as a red flag. 7 Q. Okay. Fair enough. 8 Did you, when it was published, to this 9 journal itself, the Journal of Biomedical Materials 10 Research, or any other medical journal, did you 11 write -- have you ever written a letter to the 12 editor, criticizing the methodology and/or results 13 of this paper? 14 A. Could you clarify the question? I 15 just -- have I ever written about this particular 16 paper to anybody? 17 Q. Yes. 18 A. No, I have not. 19 Q. Okay. Earlier, when I asked you 20 if you did your own research including PubMed, for 21 example, when you did your PubMed research, did 22 your search terms include those that would have 23 brought up this paper? 24 A. My search would be at least three 25 months ago and I can't recall the exact terms that</p> | <p style="text-align: right;">Page 72</p> <p>1 any individuals that you would consider peers in 2 your specialty regarding Dr. Iakovlev's methodology 3 and conclusions? 4 A. No, I have not. 5 Q. Based upon all the negative 6 answers you have shared with me, would you agree 7 that the criticisms that you have of his 8 methodology and his conclusions are limited to your 9 expert report in this litigation and your testimony 10 today? 11 MR. DAVIS: Object to the form. 12 THE WITNESS: I have not expressed my 13 reservations or criticisms about his report outside 14 of this process. 15 BY MR. RESTAINO: 16 Q. Okay. If you would turn to your 17 expert report which has been marked as Exhibit 18 Number 6, and turn to page 4. 19 You have a section there, The Practice 20 of Surgical Pathology - Technical Aspects. Do you 21 see that, sir? And your second full paragraph 22 starts with: 23 "Resecting human tissues may 24 show some retraction following 25 resection." [As read.]</p> |
| <p style="text-align: right;">Page 71</p> <p>1 I used. 2 Q. Okay. 3 A. As I recall, I believe I used the 4 terms "vaginal mesh" and "mesh", and whether this 5 paper was brought up or not, I can't recall. 6 Q. Fair enough. 7 At any time since this paper was 8 published online and you were writing your expert 9 report and preparing for today's deposition, have 10 you gone online to see how many papers have cited 11 Dr. Iakovlev's paper? 12 A. No, I have not. 13 MR. DAVIS: Object to the form. 14 BY MR. RESTAINO: 15 Q. As you sit here today, do you have 16 an understanding of how many times this paper has 17 now been cited in the peer-reviewed medical 18 literature? 19 A. I have not inquired about that. 20 Q. As you sit here today, do you know 21 if anyone has written any letter to the editor of 22 the journal, criticizing Dr. Iakovlev's methodology 23 and/or work? 24 A. I don't know of any such letter. 25 Q. Have you had any discussions with</p> | <p style="text-align: right;">Page 73</p> <p>1 Is that correct? 2 A. Mm-hmm. 3 --- (Court reporter appeals.) 4 MR. DAVIS: Say 'yes'. 5 THE WITNESS: Yes. 6 BY MR. RESTAINO: 7 Q. Jeez. 8 A. Sorry. 9 Q. Now, you write -- well, is it true 10 that you wrote, "Resected human tissues may show 11 some retraction," utilizing "may show" because 12 human tissues don't always retract following a 13 retraction -- resection; correct? 14 A. I think the nature of the resected 15 human tissue would influence the amount of 16 retraction that occurred following resection. 17 Q. And you write "some retraction" 18 because different tissues retract to different 19 degrees. 20 And by meaning "different tissues", 21 dermatological tissue retracts diff- -- assuming 22 they are all handled in the same way at the -- in 23 the operating theatre, the surgeon removes it, 24 hands it to either the circulating nurse or the 25 scrub nurse, and it's dealt with in the same manner</p> |

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| <p style="text-align: right;">Page 86</p> <p>1 foreign body reaction is virtually ubiquitous when 2 you implant something like mesh. 3 When you start to go beyond that and 4 say that varying degrees and individual, I don't 5 know of surgical pathologic data that supports 6 that; that somebody has set out to measure events 7 and correlate it with symptomatology in particular. 8 It's a statement. May -- may or may 9 not be correct. 10 Q. Are you familiar with published 11 literature wherein women have -- I guess it's 12 redundant for me to be saying women to have vaginal 13 mesh excised - but vaginal mesh is excised in some 14 women years after implantation because of foreign 15 body reaction? Have you read that literature? 16 MR. DAVIS: Object to the form. 17 THE WITNESS: I'm sure there are women 18 who have had their vaginal mesh excised. 19 I am not sure if it was excised 20 precisely because there was a foreign body giant 21 cell reaction or because of other symptomatology. 22 More likely, the latter. 23 BY MR. RESTAINO: 24 Q. Okay. I think we can revisit that 25 with some of the later questions we have.</p> | <p style="text-align: right;">Page 88</p> <p>1 surgical pathology material is 2 derived from living human patients, 3 potential confounding variables can 4 rarely be fully controlled or 5 eliminated." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. And that is one of your criticisms 9 of Dr. Iakovlev's published paper; that it is, in 10 fact, an observational study; correct? 11 A. Yes. You could call it a 12 "criticism". Perhaps a better word would be 13 "limitation". 14 Q. Okay. Do you feel that that 15 limitation decreases the value of the study? 16 A. Since Dr. Iakovlev has gone on to 17 try and draw correlations between the surgical 18 pathologic findings and symptomatology, yes. 19 Q. Okay. Now if we could go back to 20 the Hill paper, the "Histopathology of excised 21 midurethral sling mesh", which is Exhibit 11. 22 A. Yes. 23 Q. This is also an observational 24 study, is it not? 25 A. Yes, it is.</p> |
| <p style="text-align: right;">Page 87</p> <p>1 If you would turn to page 13 of your 2 expert report, and there's a section there you 3 titled Response to Dr. Iakovlev's published Journal 4 Medical Materials Research Paper. 5 That's the paper we have been 6 discussing; correct, sir? 7 A. Mm-hmm. 8 --- (Court reporter appeals.) 9 MR. DAVIS: Be sure to say -- 10 THE WITNESS: Yes. 11 BY MR. RESTAINO: 12 Q. Okay. And you write in the first 13 section there: 14 "Research papers using surgical 15 pathology specimens are often 16 observational studies, and this 17 paper is no exception. 18 Observational studies in surgical 19 pathology frequently consist of 20 reviewing a cohort of cases from 21 patients with a particular condition 22 or disease, and then seeking to make 23 correlations or associations with 24 clinical symptomatology, findings, 25 or outcome. Since the research</p> | <p style="text-align: right;">Page 89</p> <p>1 Q. If you look at "Methods" in the 2 abstract, they describe this as: 3 "...a retrospective 4 case-control study of women who 5 underwent excision of midurethral 6 sling mesh between 2008 and 2013." 7 Correct? 8 A. Mm-hmm. Correct. 9 Q. Dr. Iakovlev's paper is a 10 retrospective study, also; correct? 11 A. Correct. 12 Q. Now, the utilizing your language 13 in your expert report that we just read from, the 14 same "potential confounding [factor] variables 15 which can rarely be fully controlled or 16 eliminated", as you apply to Dr. Iakovlev's paper, 17 also apply to the Hill paper which is your 18 reference 10 that you are relying upon for your 19 expert opinion; correct? 20 MR. DAVIS: Object to the form. 21 THE WITNESS: The Hill paper did go 22 further, though, and had good clinical data to put 23 together with their histopathologic obligations. 24 BY MR. RESTAINO: 25 Q. And you understand that there are</p> |

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| <p style="text-align: right;">Page 90</p> <p>1 experts on the other side who also believe that 2 Dr. Iakovlev's paper has good clinical data to go 3 with his results? 4 MR. DAVIS: Object to the form. 5 THE WITNESS: With respect to the paper 6 that we are discussing of his, I do not see 7 clinical data which is evident in the Hill paper. 8 BY MR. RESTAINO: 9 Q. Okay. You agree that they are 10 both retrospective analyses? 11 A. Yes. 12 Q. You agree that they both have 13 potential for confounding variables in that they 14 are, (a), observational studies; (b), 15 retrospective studies with all the epidemiological 16 biases that that entails; correct? 17 MR. DAVIS: Object to the form. 18 THE WITNESS: They share 19 characteristics of observational and retrospective 20 studies, but the Hill paper has gone further and 21 collected clinical data and grouped them into three 22 groups, which is absent from Iakovlev's paper. 23 BY MR. RESTAINO: 24 Q. Now, when you say that the Hill 25 paper also includes clinical data, the authors of</p> | <p style="text-align: right;">Page 92</p> <p>1 report, the authors are -- the authors were unable, 2 in 45 percent of the cases, to analyze potential 3 risk factors that may have led to increased levels 4 of inflammation, including the date of the index 5 mesh placement, because there's acute inflammation 6 associated with surgery; correct? 7 MR. DAVIS: Object to the form. 8 THE WITNESS: Acute inflammation is 9 usually seen upon initial insertion of the mesh, 10 yes. 11 BY MR. RESTAINO: 12 Q. And the type of mesh utilized; 13 there are different inflammatory responses 14 dependent upon the type of mesh utilized. 15 Would you agree? 16 A. I'm not an expert in the 17 examination of -- of mesh. 18 Q. And there's -- 19 A. Research-wise. 20 Q. Forgive me. I'm sorry. I didn't 21 mean to interrupt. 22 And the other potential risk factor is 23 the surgical approach that was utilized; whether it 24 was transobturator or retropubic can make a 25 difference.</p> |
| <p style="text-align: right;">Page 91</p> <p>1 the Hill paper did not have access to all of the 2 index surgical operative reports, did they? 3 A. I can't recall that. 4 Q. Would that be important to you? 5 A. Sorry. Can you repeat that 6 question again? 7 Q. The authors of the Hill paper did 8 not have access to all of the index surgical 9 operative reports; therefore, they had to rely upon 10 subject recall, as documented in the electronic 11 medical record, for some of the data. 12 And that is a weakness and source of 13 bias in a retrospective case-control study, is it 14 not? 15 MR. DAVIS: Object to the form. 16 THE WITNESS: The... There are often 17 limitations in the amount of clinical data one can 18 obtain, either through a practical availability or 19 ethic board approval, but this doesn't change the 20 fact that they did get some clinical data which is 21 not present in Iakovlev's paper. 22 BY MR. RESTAINO: 23 Q. In fact, they were able to obtain 24 only 55 percent of the index surgical operative 25 reports, and without the index operative surgical</p> | <p style="text-align: right;">Page 93</p> <p>1 Wouldn't you agree? 2 A. I'm not a urogynecologist, so I 3 defer that question. 4 Q. Okay. And additionally, not all 5 of the subjects who underwent revision of their 6 sling had pathological specimens for review, 7 introducing yet another form of bias. 8 Did you know that? 9 MR. DAVIS: Object to the form. 10 THE WITNESS: You're outlining a number 11 of concerns about the availability of clinical 12 data, but this doesn't change the basic underlying 13 fact that they did the best they could to get at 14 least some clinical data, which was not present at 15 all in Iakovlev's study. 16 BY MR. RESTAINO: 17 Q. But the fact that they couldn't 18 get it all introduces bias, that you cannot sit 19 here and tell us how strong or important that bias 20 was. 21 Don't you agree? 22 MR. DAVIS: Object to the form. 23 THE WITNESS: There would be very few 24 clinicopathologic studies in the literature that 25 did not have some sort of bias.</p> |

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| <p style="text-align: right;">Page 94</p> <p>1 Stating bias does not make this study 2 unique. 3 BY MR. RESTAINO: 4 Q. And the fact that they rely upon 5 medical records in a retrospective fashion 6 introduces the potential for misclassification 7 bias, also, does it not? 8 A. Yes. 9 Q. So whereas you criticize 10 Dr. Iakovlev's paper in your report as being an 11 observational study with its weaknesses, you rely 12 upon Hill, yet your report does not inform the 13 judge that they didn't have 45 percent of the 14 operative reports, so therefore they didn't know 15 the index surgical date, so therefore they didn't 16 know if they were looking at acute postop 17 inflammation or inflammation secondary to a foreign 18 body reaction downstream, and the patients may have 19 had different surgical approaches. And there are 20 differences in the literature between the 21 retropubic approach and the transobturator 22 approach. And they had to rely strictly upon 23 medical records which could be incomplete and 24 introduce misclassification bias. 25 But your expert report does not state</p> | <p style="text-align: right;">Page 96</p> <p>1 colleagues does not adhere to good 2 scientific practice." 3 Did I read that correctly? 4 A. Yes, you do. 5 Q. This paper was peer-reviewed and 6 published in a peer-reviewed medical journal; 7 correct? 8 A. And I've already expressed to you 9 that the issue around peer review and its quality 10 and success is under serious question in 2017. 11 Q. Is there any question that you've 12 been aware of as to the quality of publications 13 from the Journal of Biomedical Materials Research 14 or -- 15 A. I'm not acquainted with the 16 journal, but I have great concerns about any 17 journal, which even in the Materials and Methods 18 section, allows a section to be called "Measurement 19 of degradation layer thickness" before the 20 presentation of any results whatsoever, which is in 21 flagrant violation of the initial question which is 22 being asked: Is there degradation? 23 And then, within their "Materials and 24 methods" section, they have already concluded that 25 there is a degradation layer.</p> |
| <p style="text-align: right;">Page 95</p> <p>1 any of that, does it? 2 MR. DAVIS: Object to the form. 3 THE WITNESS: I did not go into the 4 Hill report in detail, but I would like to point 5 out some of the biases which are in Mr. -- or 6 Dr. Iakovlev's. 7 BY MR. RESTAINO: 8 Q. And we're going to get to them and 9 you'll have your -- you will have an opportunity to 10 discuss them further, which you already have done 11 in your expert report. 12 Now, at the... On page 13, at the end 13 of your first paragraph, you write: 14 "In surgical pathology research 15 papers observations must be reported 16 objectively in the 'results 17 section'. Interpretation of the 18 results and hypotheses generated 19 from these interpretations must be 20 restricted to the subsequent 21 'discussion' section." 22 Did I read that correctly? 23 A. Yes did you. 24 Q. You then go on to say that: 25 "This paper by Dr. Iakovlev and</p> | <p style="text-align: right;">Page 97</p> <p>1 Q. Would you agree that within a 2 medical article submitted for peer review and then 3 publication to the general scientific medical 4 community, what is important in the scientific 5 method is the development of a hypothesis, the 6 testing of the hypothesis, the reporting of 7 conclusions, the peer review of those conclusions 8 in publication, and replication? 9 Would you agree that they are the 10 component parts of the scientific method? 11 MR. DAVIS: Object to the form. 12 THE WITNESS: Yes. Having an initial 13 hypothesis, developing the methods, the results, 14 and then answering the question is important. 15 This paper mixes hypothesis, materials 16 and methods, and results. 17 BY MR. RESTAINO: 18 Q. The paper reports data for the 19 general scientific and medical community, as a 20 whole, to look at, analyze, attempt to replicate if 21 the methods are appropriately described, and then 22 become generally accepted. 23 Why is it important to you where data 24 is presented? 25 MR. DAVIS: Object to the form.</p> |

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| <p style="text-align: right;">Page 98</p> <p>1 THE WITNESS: What's important to me is 2 that the data be presented in an objective fashion 3 and then the hypothesis tested in the discussion. 4 This paper seemingly sets out to prove 5 degradation by use of the term, not only within 6 "Results" section, but also in the "Materials and 7 methods". 8 BY MR. RESTAINO: 9 Q. Did you review the abstract of the 10 paper? 11 A. I did. 12 Q. And does the abstract of the paper 13 itself lay out for the reader the hypothesis, the 14 methodology, the observations and the conclusions? 15 A. I would have to reread it again, 16 but I would assume it would. 17 Q. Okay. And you write that: 18 "The authors are unable to 19 separate objective results from 20 subjective interpretations." 21 [As read.] 22 Do you recall that? 23 A. Yes. 24 Q. Is that your opinion today; that 25 Dr. Iakovlev and his colleagues are unable to</p> | <p style="text-align: right;">Page 100</p> <p>1 is in the context of your expert opinions in this 2 litigation. 3 Would you agree? 4 MR. DAVIS: Object to the form. 5 THE WITNESS: Yes, but let me 6 elaborate. 7 It's not uncommon for a critical 8 academic pathologist to have concerns about 9 published papers if -- and the methods that may 10 have been used. 11 We're all... 12 BY MR. RESTAINO: 13 Q. You would agree that that would -- 14 MR. DAVIS: Wait. 15 MR. RESTAINO: Oh. I'm sorry. 16 MR. DAVIS: Were you through with your 17 answer? 18 THE WITNESS: There -- as my old 19 chairman used to say, there's never been a 20 perfectly published paper. 21 BY MR. RESTAINO: 22 Q. Your statement about concerns, 23 though, would apply to other medical specialties, 24 would it not? 25 Let me elaborate.</p> |
| <p style="text-align: right;">Page 99</p> <p>1 differentiate between objectivity and subjectivity? 2 A. Yes. 3 I think when we get to the "Results" 4 section on page 3, in the very first sentence of 5 their second paragraph, they have already used the 6 -- the phrase "circumferential outer layer of 7 degraded polypropylene" before they presented the 8 rest of the results. 9 That statement, in my opinion, should 10 only have been made in the discussion. 11 You do not set out a hypothesis and 12 then conclude within the first sentence of your 13 second paragraph of results that your hypothesis 14 has been proven without first presenting the data. 15 Q. By putting language in differing 16 sections of a peer-reviewed medical record -- 17 medical article, in your expert opinion, does that 18 invalidate the data? 19 A. It throws into question the 20 derivation and interpretation of the data. 21 Q. A question which no letter to the 22 editor has yet to raise nor have you brought up 23 with any other colleague, your department chairman 24 or the journal itself. 25 The only time the criticism has come up</p> | <p style="text-align: right;">Page 101</p> <p>1 Do you review, as part of your general 2 professional activity, surgical papers? 3 A. I do not review surgical papers. 4 My reviews would largely be in surgical and 5 cytopathology. 6 Q. Could you foresee a situation 7 where a new surgical procedure is published in the 8 peer-reviewed literature and a surgeon in that 9 specialty looks carefully at the methodology to 10 determine whether it makes sense and is a procedure 11 that he or she may want to try on his or her next 12 patient? 13 MR. DAVIS: Object to the form. 14 THE WITNESS: I am not sure I 15 understand what your question is. 16 BY MR. RESTAINO: 17 Q. Going back to the statement that 18 you made as -- as why it's important for 19 pathologists to look for certain things in papers, 20 generally I'm asking, that applies to all medical 21 and scientific specialties, does it not? 22 A. Yes. 23 Q. And if the scientific method is 24 followed and if there's hypothesis and testing and 25 results and conclusions that undergoes peer review</p> |

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| <p style="text-align: right;">Page 102</p> <p>1 and then subject to criticism by the general 2 scientific or medical community, then the 3 scientific method has been fulfilled, has it not? 4 A. But that was not the case here. 5 This case did not follow the scientific 6 method. It put forward a hypothesis and then 7 muddled the waters throughout the "Materials and 8 methods" and "Results" sections. 9 Q. The paper, in your opinion, did 10 that, but the scientific method employed by the 11 researchers are the thinking of an hypothesis, the 12 actual testing of the hypothesis, the actual 13 observation of results, the actual deduction of 14 conclusions, then writing the paper for peer 15 review. 16 That scientific method has been 17 fulfilled in this paper. It's just your criticism 18 of where they put the language; correct? 19 MR. DAVIS: Object to the form. 20 THE WITNESS: They did attempt to write 21 a scientific paper. 22 BY MR. RESTAINO: 23 Q. And it was published in the 24 peer-reviewed medical literature? 25 A. It was published in a</p> | <p style="text-align: right;">Page 104</p> <p>1 BY MR. RESTAINO: 2 Q. Do you agree that the mesh itself, 3 as a foreign object, and the body's reaction to the 4 foreign object results in damage to tissue? 5 A. The placement of the mesh and the 6 nature of the surgery does damage tissue, but 7 results in a healing process characterized by some 8 fibrosis and foreign body reaction to restore 9 tissue integrity. 10 Q. And taking the mesh out of your 11 answer, that's the body's response to every 12 surgery, is it not? 13 A. Correct. 14 Q. The introduction of mesh adds a 15 second component to the healing process, and that's 16 the foreign body reaction. 17 Do you agree? 18 A. Yes. 19 Q. And a foreign body reaction is a 20 normal pathological response. 21 Is that a fair way of describing it? 22 A. It's a ubiquitous pathologic 23 response to the foreign material, yes. 24 Q. Okay. And a foreign body reaction 25 -- I'm sorry.</p> |
| <p style="text-align: right;">Page 103</p> <p>1 peer-reviewed journal. 2 MR. RESTAINO: Okay. Let's go ahead 3 and take our next break. 4 ---Recess at 11:04 a.m. 5 ---On resuming at 11:11 a.m. 6 BY MR. RESTAINO: 7 Q. Welcome back, Doctor. 8 A. Thank you. 9 Q. We could continue on page 14 of 10 your report, the section titled "Response to 11 Dr. Iakovlev's expert report". 12 You write: 13 "In the introduction of his 14 summary opinion, his expert report, 15 Dr. Iakovlev states that, 'The mesh 16 itself, as a foreign object, and the 17 body reaction to the mesh damaged 18 the tissues in a critical anatomical 19 location.'" [As read.] 20 Do you agree with that statement? 21 MR. DAVIS: Object to the form. 22 Do you mean, does he agree that 23 Dr. Iakovlev said that? 24 MR. RESTAINO: Let me rephrase that. 25 That's an excellent objection.</p> | <p style="text-align: right;">Page 105</p> <p>1 Inflammation following surgery is 2 typically acute in nature if there's isn't any 3 postoperative sequelae. 4 Would you agree? 5 A. It initiates with acute and then 6 moves on to a chronic phase, as I outlined in my 7 report. 8 Q. And acute inflammation following 9 surgery is normal pathology? 10 A. It's a -- yes, normal pathologic 11 response. 12 Q. Without that acute inflammation, 13 there truly isn't healing; correct? 14 A. Correct. 15 Q. Once the inflammation goes past a 16 certain point, it's now pathological inflammation, 17 chronic in nature. 18 Do you agree with that? 19 A. I think you're drawing a 20 distinction which I'm uncertain about. 21 The chronic inflammation is as much a 22 normal part of the pathologic and healing reaction 23 as the acute. 24 Q. Let me try to make it a little 25 clearer from my end and easier for you to answer</p> |

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| <p style="text-align: right;">Page 110</p> <p>1 disappear.</p> <p>2 BY MR. RESTAINO:</p> <p>3 Q. On page 14, right above the</p> <p>4 section "Response to Dr. Iakovlev's Expert Report",</p> <p>5 that one-sentence paragraph, you write:</p> <p>6 "In this paper Dr. Iakovlev</p> <p>7 concludes that the mechanism leading</p> <p>8 to mesh-related complications is</p> <p>9 unclear, through his statement,</p> <p>10 '...the exact mechanisms of these</p> <p>11 late complications are yet to be</p> <p>12 understood,'."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes, you did.</p> <p>15 Q. Now, in fact, if you turn to page</p> <p>16 10 of Dr. Iakovlev's paper, there's a section on</p> <p>17 the left column... Are you there, sir?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. ...that says "Clinical</p> <p>20 significance of polypropylene degradation".</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And in the second paragraph where</p> <p>24 I believe you're attempting to quote from, he</p> <p>25 writes:</p> | <p style="text-align: right;">Page 112</p> <p>1 abdominal mesh and vaginal mesh that develop</p> <p>2 complications years after implantation; correct?</p> <p>3 A. I accept that.</p> <p>4 Q. Page 15 of your report, as you</p> <p>5 continue on, your very first sentence states:</p> <p>6 "Tissue damage is a consequence</p> <p>7 of any surgery, including</p> <p>8 incontinence surgery, and would</p> <p>9 occur with non-mesh surgery for</p> <p>10 incontinence, as well."</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes, you did.</p> <p>13 Q. Surgery for incontinence which</p> <p>14 does not involve mesh, though, would not have the</p> <p>15 foreign body reaction to the mesh to contend with.</p> <p>16 Wouldn't you agree?</p> <p>17 A. Correct. I mean, the surgery</p> <p>18 still involves an incision and all the acute</p> <p>19 inflammation, granulation tissue, fibrosis that I</p> <p>20 described earlier in my report.</p> <p>21 Q. Would you agree that the host</p> <p>22 reaction during a surgery that involves mesh is</p> <p>23 different than the host reaction to surgery in the</p> <p>24 pelvis that does not include mesh?</p> <p>25 MR. DAVIS: Object to the form.</p> |
| <p style="text-align: right;">Page 111</p> <p>1 "The clinical descriptions</p> <p>2 provided with the specimens</p> <p>3 indicated that in many cases,</p> <p>4 mesh-related complications develop</p> <p>5 several years after mesh</p> <p>6 implantation. The exact mechanisms</p> <p>7 of these late complications are yet</p> <p>8 to be understood, however factors</p> <p>9 accumulating over time need to be</p> <p>10 considered as primary contributors."</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes, you did.</p> <p>13 Q. That's not what you quoted in your</p> <p>14 paper.</p> <p>15 A. I quoted --</p> <p>16 MR. DAVIS: Object to form.</p> <p>17 THE WITNESS: I quoted partially. I</p> <p>18 didn't put in the entire sentence.</p> <p>19 BY MR. RESTAINO:</p> <p>20 Q. Okay. Now, the medical literature</p> <p>21 itself is replete with reports of mesh-related</p> <p>22 complications developing several years after</p> <p>23 implantation, is it not?</p> <p>24 A. I have become aware of them.</p> <p>25 Q. And that literature includes both</p> | <p style="text-align: right;">Page 113</p> <p>1 THE WITNESS: Yes. I think, by nature,</p> <p>2 you do have a foreign body. There is going to be a</p> <p>3 different appearance by microscopy.</p> <p>4 MR. RESTAINO: I would like to mark as</p> <p>5 the next exhibit - I think we're...</p> <p>6 THE COURT REPORTER: 12.</p> <p>7 MR. RESTAINO: 12?</p> <p>8 THE COURT REPORTER: Mm-hmm.</p> <p>9 MR. RESTAINO: Okay. Article titled</p> <p>10 Foreign Body Reaction to Biomaterials by James M.</p> <p>11 Anderson, et al., published in Seminars of</p> <p>12 Immunology in 2008.</p> <p>13 ---EXHIBIT NO. 12: Article entitled</p> <p>14 Foreign Body Reaction to Biomaterials, by James M.</p> <p>15 Anderson, et al., published in Seminars of</p> <p>16 Immunology in 2008.</p> <p>17 BY MR. RESTAINO:</p> <p>18 Q. I represent to you that I did not</p> <p>19 find this referenced in your expert report, nor did</p> <p>20 I find it in your general reliance list.</p> <p>21 Do you recall seeing this paper?</p> <p>22 A. I do not.</p> <p>23 Q. In your search of PubMed and</p> <p>24 writing for expert reports, would this not be a</p> <p>25 paper that would come up using your keywords?</p> |

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| <p style="text-align: right;">Page 118</p> <p>1 Does that sound familiar?</p> <p>2 A. I do not recall that.</p> <p>3 I do recall -- I don't recall the</p> <p>4 figures. I remember a Canadian study.</p> <p>5 Q. Okay. We'll get to that in a</p> <p>6 moment and we'll discuss it.</p> <p>7 You then write that:</p> <p>8 "Dr. Iakovlev has identified no</p> <p>9 histological feature unique to</p> <p>10 certain complications, no matter</p> <p>11 their frequency." [As read.]</p> <p>12 What unique histological feature would</p> <p>13 you expect to see in a foreign body reaction?</p> <p>14 In fact, it's typically a universal</p> <p>15 reaction, whether it's a heart valve, an artificial</p> <p>16 knee. If it's mesh, wherever it is in the body,</p> <p>17 there's a normal foreign body reaction; correct?</p> <p>18 MR. DAVIS: Object to the form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. RESTAINO:</p> <p>21 Q. So I guess I'm confused in what</p> <p>22 would you have liked to have seen described that</p> <p>23 would be unique to a foreign -- to a mesh foreign</p> <p>24 body reaction?</p> <p>25 A. I --</p> | <p style="text-align: right;">Page 120</p> <p>1 word you used was the "ubiquitous" pathological</p> <p>2 response, which is a pathological response, but</p> <p>3 it's normal?</p> <p>4 MR. DAVIS: Object to the form.</p> <p>5 BY MR. RESTAINO:</p> <p>6 Q. Is that correct?</p> <p>7 A. Yes. We agree, it's a normal</p> <p>8 pathologic response.</p> <p>9 Q. So I am confused where in that</p> <p>10 continuum you would expect for Dr. "I" or any other</p> <p>11 researcher to come up with a unique observation</p> <p>12 that indicates, 'Aha. This is a foreign body</p> <p>13 reaction due to a mesh.'</p> <p>14 MR. DAVIS: Object to the form.</p> <p>15 THE WITNESS: He has not identified any</p> <p>16 particular pathologic finding with symptomatology,</p> <p>17 from my reading.</p> <p>18 BY MR. RESTAINO:</p> <p>19 Q. Continuing on page 15, towards the</p> <p>20 bottom -- oh, I'm sorry. Let me back up and I will</p> <p>21 preface it by saying that it's your opinion:</p> <p>22 "Dr. "I"'s opinion's are</p> <p>23 counter to professional</p> <p>24 organizations of physicians and</p> <p>25 surgeons who treat stress urinary</p> |
| <p style="text-align: right;">Page 119</p> <p>1 MR. DAVIS: Object to the form.</p> <p>2 THE WITNESS: I think the better</p> <p>3 question is: What -- why couldn't Dr. "I" find</p> <p>4 something to explain the pain specifically instead</p> <p>5 of hypothesizing, as he does without evidence, that</p> <p>6 this reaction is necessarily the central event in</p> <p>7 the development of symptomatology?</p> <p>8 BY MR. RESTAINO:</p> <p>9 Q. It's widely reported that there's</p> <p>10 a foreign body reaction to the mesh; agreed?</p> <p>11 A. Agreed.</p> <p>12 Q. And it's widely reported that the</p> <p>13 foreign body reaction can be acute and/or chronic</p> <p>14 in nature?</p> <p>15 A. By definition, a foreign body</p> <p>16 reaction is chronic.</p> <p>17 Q. And there are patients who, with a</p> <p>18 chronic foreign body reaction, develop pain years</p> <p>19 after implantation to the point where the mesh has</p> <p>20 to be removed; correct?</p> <p>21 MR. DAVIS: Object to the form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. RESTAINO:</p> <p>24 Q. And in that situation, the</p> <p>25 patients present with the normal or I think the</p> | <p style="text-align: right;">Page 121</p> <p>1 incontinence who have recently</p> <p>2 reaffirmed their support for the use</p> <p>3 of polypropylene mid-urethral</p> <p>4 slings."</p> <p>5 Is that your opinion?</p> <p>6 A. Yes.</p> <p>7 Q. Have you ever seen or heard</p> <p>8 Dr. Iakovlev write or say that in his opinion,</p> <p>9 these mesh devices should be taken off the market?</p> <p>10 A. No, I have not heard him say that.</p> <p>11 Q. Does he state that anywhere in his</p> <p>12 expert report?</p> <p>13 A. Not that I'm aware of.</p> <p>14 Q. In fact, in his papers and in his</p> <p>15 expert report, as a pathologist, Dr. Iakovlev</p> <p>16 describes pathology which, as we started off the</p> <p>17 deposition by saying, is the study of disease</p> <p>18 hopefully in order to prevent or treat disease;</p> <p>19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. So in support of his opinion, you</p> <p>22 reference in your expert report, the May 2017</p> <p>23 position paper by the Royal Australian and New</p> <p>24 Zealand College of Obstetricians and Gynecologists</p> <p>25 known at RANZCOG, all capital, R-A-N-Z-C-O-G.</p> |

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| <p style="text-align: right;">Page 126</p> <p>1 up with the term "foreign body reaction". And</p> <p>2 Dr. Iakovlev does not describe the incidence or</p> <p>3 recommend removal of mesh.</p> <p>4 Where do these two -- does this</p> <p>5 organization and Dr. Iakovlev disagree?</p> <p>6 MR. DAVIS: Object to the form.</p> <p>7 THE WITNESS: My purpose in citing this</p> <p>8 paper was to put the context of current mesh use</p> <p>9 within the medical profession in order to give a</p> <p>10 context to Dr. "I"'s research and opinions.</p> <p>11 BY MR. RESTAINO:</p> <p>12 Q. You actually write:</p> <p>13 "Dr. "I"'s opinions are counter</p> <p>14 to professional organizations of</p> <p>15 physicians and surgeons who treat</p> <p>16 stress urinary incontinence."</p> <p>17 [As read.]</p> <p>18 Where are his opinions counter to</p> <p>19 anything that's in that organization's position</p> <p>20 statement?</p> <p>21 MR. DAVIS: Object to the form.</p> <p>22 THE WITNESS: I think if one reads his</p> <p>23 -- some of his statements are sufficiently broad as</p> <p>24 to give rise to the concern of use of mesh, at all.</p> <p>25 BY MR. RESTAINO:</p> | <p style="text-align: right;">Page 128</p> <p>1 reported chronic pain to occur in</p> <p>2 1.8 percent of patients receiving a</p> <p>3 retropubic sling (such as TVT) and</p> <p>4 in 4.3 percent of patients receiving</p> <p>5 transobturator sling (such as</p> <p>6 TVT-O). [Reference 19]</p> <p>7 "Dr. Iakovlev also ignores a</p> <p>8 recent population-based study</p> <p>9 published from Ontario, Canada,</p> <p>10 where both he and I work, showing</p> <p>11 the overall rate of mesh removal or</p> <p>12 revision of SUI slings to be 2.2</p> <p>13 percent in the 59,887 women studied.</p> <p>14 [Reference 23]." [As read.]</p> <p>15 Do you see that, sir?</p> <p>16 A. Yes.</p> <p>17 Q. Now, his expert report is on the</p> <p>18 pathology of mesh, not on the incidence of mesh</p> <p>19 excision.</p> <p>20 Would you agree?</p> <p>21 A. Yes.</p> <p>22 Q. And his paper in the Journal of</p> <p>23 Biomaterials Research also has to do with pathology</p> <p>24 and not epidemiology.</p> <p>25 Do you agree?</p> |
| <p style="text-align: right;">Page 127</p> <p>1 Q. Do you not believe that Dr. "I"</p> <p>2 presents, with his coworkers, his basis for his</p> <p>3 beliefs regarding the cause of pain that patients</p> <p>4 experience with mesh?</p> <p>5 A. I believe he has attempted that,</p> <p>6 yes.</p> <p>7 Q. And as a pathologist, the study of</p> <p>8 the cause of disease is an important factor;</p> <p>9 correct?</p> <p>10 A. When pursued in a scientifically</p> <p>11 valid fashion, yes.</p> <p>12 Q. And have you -- you criticize his</p> <p>13 paper that we have been discussing regarding the</p> <p>14 language of -- the placement of certain language.</p> <p>15 Have you reviewed all of his papers on</p> <p>16 transvaginal mesh?</p> <p>17 A. I have not.</p> <p>18 Q. Now, if I can find it... Ah, yes.</p> <p>19 On page 16, there's a full paragraph,</p> <p>20 the very first full paragraph, and you indicate</p> <p>21 there that:</p> <p>22 "Dr. Iakovlev fails to</p> <p>23 acknowledge the low complications</p> <p>24 from mesh devices yet he himself</p> <p>25 co-authored a review article that</p> | <p style="text-align: right;">Page 129</p> <p>1 A. Yes.</p> <p>2 Q. And you're not -- are you saying</p> <p>3 that with the population-based study that occurred</p> <p>4 here in Canada, that there -- with the 2.2 percent</p> <p>5 removal or revision rate, are you saying that</p> <p>6 that's clinically insignificant?</p> <p>7 A. No, I'm not saying it's clinically</p> <p>8 insignificant.</p> <p>9 Quite to the contrary, I have</p> <p>10 acknowledged that there are cases of removal and</p> <p>11 re-excision of the mesh.</p> <p>12 What I am suggesting is that by failing</p> <p>13 to identify the incidence of serious complications,</p> <p>14 Dr. "I" has not provided the context to place his</p> <p>15 pathologic findings in the overall medical use and</p> <p>16 picture of vaginal slings, and that the selective</p> <p>17 use of data and the omission of data is, in my</p> <p>18 opinion, not consistent with the best medical</p> <p>19 papers.</p> <p>20 Q. In the context of the litigation</p> <p>21 and his expert report, do you understand that there</p> <p>22 are epidemiological experts for each side</p> <p>23 presenting data on incidence and prevalence?</p> <p>24 A. I'm not surprised. I wasn't aware</p> <p>25 there was.</p> |

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| <p style="text-align: right;">Page 154</p> <p>1 you ever look at a paper by Feiner, F-e-i-n-e-r, 2 and Maher, M-a-h-e-r, titled Vaginal mesh 3 contraction: Definition, clinical presentation, and 4 management, which I will ask the court reporter to 5 mark as the last exhibit. 6 MR. DAVIS: Object to the form. 7 THE WITNESS: I don't recall that. 8 ---EXHIBIT NO. 16: A paper by Feiner 9 and Maher, titled Vaginal mesh contraction: 10 Definition, clinical presentation, and management. 11 BY MR. RESTAINO: 12 Q. I will put to you that it's -- 13 this paper is not listed in your expert report nor 14 is it in your general reliance list. 15 If I can direct your attention to the 16 conclusion of the abstract: 17 "Vaginal mesh contraction is a 18 serious complication after prolapse 19 repair with armed polypropylene mesh 20 that is associated with substantial 21 morbidity, frequently requiring 22 surgical intervention. Research and 23 development is urgently needed for 24 newer graft materials with 25 diminished shrinkage properties."</p> | <p style="text-align: right;">Page 156</p> <p>1 Q. And in your search for writing 2 your expert opinion where, in your opinion, there's 3 little to no evidence that mesh contracts, you did 4 not find the paper "Vaginal mesh contraction"; do 5 you agree? 6 A. I must not have. 7 MR. RESTAINO: I have no further 8 questions. 9 MR. DAVIS: Okay. 10 MR. RESTAINO: How's that for timing? 11 MR. DAVIS: You did great. 12 Let's just take a break for a second. 13 ---Recess at 12:16 p.m. 14 ---On resuming at 12:20 p.m. 15 EXAMINATION BY MR. DAVIS: 16 Q. Dr. Colgan, as you know, I'm Paul 17 Davis. I have just a few follow-up questions. 18 I don't know if I wrote this down 19 accurately or not, but early on in your deposition, 20 in an answer to one of John's questions, I believe 21 I heard you say something to the effect that, 'I 22 did not hold myself out to be an expert in the 23 pathology of vaginal mesh.' 24 Whether -- do you recall saying 25 something to that effect?</p> |
| <p style="text-align: right;">Page 155</p> <p>1 [As read.] 2 Did I read that correctly? 3 A. Yes, you did. 4 Q. This is counter to your expert 5 opinion that there's no evidence that the mesh 6 contracts. 7 Would you agree? 8 MR. DAVIS: Object to the form. 9 THE WITNESS: Of course, I haven't read 10 this before, but I am struck by their "n" number is 11 only 17, which seems to contradict their statement 12 that it causes substantial morbidity when we know 13 that there are tens of thousands of such mesh, if 14 not more, used each year in North America. 15 BY MR. RESTAINO: 16 Q. But their "n" number deals with 17 their own particular study. 18 And before their study, they also have 19 a "Discussion" section where they review the 20 pertinent medical literature and the FDA 21 announcement in 2008, and then in 2008 when they 22 mention, where they describe complications; 23 correct? 24 A. I don't know. I -- you've only 25 just handed me this paper.</p> | <p style="text-align: right;">Page 157</p> <p>1 A. Yeah. And I -- yeah, I remember 2 that question. 3 Q. Can you just explain what you 4 meant by that? 5 A. So what I meant was, I'm not a 6 research expert in vaginal mesh. As has been 7 pointed out, I haven't published on it, I haven't 8 held contracts with it, I haven't done industry 9 contracts. 10 But I do -- I do have insights, as a 11 gynecologic pathologist, into foreign tissue 12 reactions and I am capable, as a 25-year-plus 13 gynecologic pathologist, to assess the validity of 14 histopathologic claims around vaginal mesh. 15 Q. As far as examining the pathology 16 of explanted meshes or specimens that had mesh in 17 them, do you have an estimate of how frequently 18 over the years, how many a year you reviewed? 19 ---[Court reporter appeals.] 20 BY MR. DAVIS: 21 Q. ...how many of those specimens 22 that you have reviewed on an annual basis, 23 approximately? 24 A. Probably no more than a dozen a 25 year. At our institution, there's three of us that</p> |

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| <p style="text-align: right;">Page 158</p> <p>1 do gynecologic pathology and I do about 60 percent 2 of it, so...</p> <p>3 Q. And for how many years would that 4 -- has that been going on?</p> <p>5 A. Well, at least 10 years for the 6 explants, I would think. Yeah.</p> <p>7 Q. Okay. With respect to the report 8 you have written and issued in this case, were the 9 opinions that you express in that report within 10 your expertise?</p> <p>11 A. Absolutely. I mean, many of those 12 opinions that I've written about is about the 13 practice of surgical pathology, histopathology in 14 general and gynecologic pathology specifically.</p> <p>15 Q. Then, with respect to your 16 opinions concerning what Dr. Iakovlev has written 17 in his report, are those opinions of yours in your 18 response to Dr. Iakovlev, are those within your 19 field of expertise?</p> <p>20 A. Yes.</p> <p>21 Q. Now, looking at your report, I 22 believe you were asked to look at page 16, at one 23 point, of your report, and where there was a 24 paragraph - I think it was the full first paragraph 25 on the page - where you pointed out that</p> | <p style="text-align: right;">Page 160</p> <p>1 So when he makes statements about 2 "vascular compartments" or "edema can lead to", he 3 really doesn't have a control group when he has 4 looked at those features, "vascular compartments" 5 and "edema", to know whether to -- whether those 6 so-called descriptions of these areas are really 7 associated with the symptomatology that he 8 conjectures is ascribed to them.</p> <p>9 He doesn't have a suitable alternative 10 group without failure.</p> <p>11 Q. As counsel opposite, I believe, 12 pointed out, that Dr. Iakovlev's report had a 13 number of photomicrographs attached to it.</p> <p>14 Do you recall that?</p> <p>15 A. Yes.</p> <p>16 Q. In those -- do you recall having 17 looked at those photomicrographs?</p> <p>18 A. Yes.</p> <p>19 Q. Those photomicrographs, in general 20 - since we don't have them here as part of the 21 exhibit today, I'll just ask you in general - are 22 they depicting reactions, you know, acute 23 inflammation in some cases, chronic inflammation in 24 other cases, that are somehow significantly 25 different from what you would see in other</p> |
| <p style="text-align: right;">Page 159</p> <p>1 Dr. Iakovlev had ignored the fact that the reported 2 chronic pain occurs in about 1.8 percent of 3 patients receiving a TVT.</p> <p>4 Can you explain to the jury why you 5 were critical of Dr. Iakovlev for not considering 6 that percentage as opposed to the large percentage 7 of ladies who have not reported pain?</p> <p>8 A. Well, I think when you read 9 Dr. "I"'s report, you're struck by its focus on why 10 mesh failed and symptomatology due to mesh failure, 11 if we call it that.</p> <p>12 And I think, and I still think it's 13 important to place into context the number of women 14 or the low percentage of women who actually have 15 complications and pain in a very common surgical 16 procedure.</p> <p>17 Q. Okay. In the field of pathology, 18 in order to establish a pathological correlate 19 between pain and something you're seeing in 20 pathology, is it customary to have a, you know, 21 comparison with some control group?</p> <p>22 A. Yeah. Many... One has to 23 understand that Dr. "I"'s research is highly biased 24 to those cases which have failed by the nature that 25 the vaginal mesh has been excised.</p> | <p style="text-align: right;">Page 161</p> <p>1 specimens that don't have mesh in them?</p> <p>2 A. No. I mean, many -- many of his 3 photomicrographs are not unexpected in a suture 4 granuloma or -- or another site of a foreign body.</p> <p>5 His captions, when he -- I believe he 6 uses terms like "damaged vessels". It indicates an 7 interpretation which would not normally be 8 justified.</p> <p>9 Q. I have one last area I want to 10 cover.</p> <p>11 You were asked some questions about the 12 position statements the RANZCOG and the AUGS and 13 the SUFU.</p> <p>14 Do you recall that in general?</p> <p>15 A. Yes.</p> <p>16 Q. And I believe counsel opposite 17 pointed out that those position statements did not 18 say anything about the subject matter of what 19 Dr. Iakovlev has opined about as far as pathology 20 associated with these slings; correct?</p> <p>21 MR. RESTAINO: Objection.</p> <p>22 THE WITNESS: Correct.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. And so, can you just explain to 25 the jury why it's important, to you, to consider</p> |

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| <p style="text-align: right;">Page 162</p> <p>1 those -- strike that. Let me start over.</p> <p>2 Can you explain to the jury why you</p> <p>3 believe it's important that Dr. Iakovlev should</p> <p>4 have considered these position statements, given</p> <p>5 that they don't mention pathology?</p> <p>6 A. Again, I think it's important to</p> <p>7 put the context of Dr. "I"'s work and conjectures</p> <p>8 in the context of the overall success of slings and</p> <p>9 it's... I...</p> <p>10 Although these are clinical statements</p> <p>11 and clinical assessments, I think we have to</p> <p>12 realize that if concerns about Dr. "I"'s pathology</p> <p>13 observations were widely shared, that they would</p> <p>14 have been reflected, even though these were</p> <p>15 clinical statements.</p> <p>16 ---[Court reporter appeals.]</p> <p>17 THE WITNESS: ...even though these were</p> <p>18 clinical statements.</p> <p>19 MR. DAVIS: That's all I have.</p> <p>20 MR. RESTAINO: Just one follow-up</p> <p>21 question.</p> <p>22 EXAMINATION BY MR. RESTAINO: (CONT'D)</p> <p>23 Q. When you indicate - paraphrasing -</p> <p>24 that you believe Dr. "I" should be taking into</p> <p>25 consideration the overall success of these slings,</p> | <p style="text-align: right;">Page 164</p> <p>1 A. You are suggesting ethically, it's</p> <p>2 very hard to get ahold of those other specimens and</p> <p>3 I'm suggesting until you have them through whatever</p> <p>4 way - autopsy or whatever - you have to be very</p> <p>5 circumspect about the conclusions you can draw from</p> <p>6 a highly biased group of pathology specimens drawn</p> <p>7 from failed slings.</p> <p>8 Q. And are you aware of any autopsy</p> <p>9 studies that have been published where they've</p> <p>10 looked at mesh during the autopsy in women who did</p> <p>11 not have presenting symptomatology?</p> <p>12 A. I do not know of any.</p> <p>13 MR. RESTAINO: No further questions.</p> <p>14 MR. DAVIS: Thank you.</p> <p>15 MR. RESTAINO: Thank you. Thank you</p> <p>16 very much.</p> <p>17 THE WITNESS: Okay.</p> <p>18 ---[Ending time: 12:31 p.m.]</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |
| <p style="text-align: right;">Page 163</p> <p>1 in fact, it's the opposite.</p> <p>2 Dr. "I", as a pathologist, is</p> <p>3 interested in the overall failure of these slings.</p> <p>4 Again, as we discussed, over 60,000 failures have</p> <p>5 occurred and, as a pathologist, that's what</p> <p>6 pathologists do; look at the cause of disease and</p> <p>7 trauma; correct?</p> <p>8 MR. DAVIS: Object to the form.</p> <p>9 THE WITNESS: Dr. "I"'s work has one</p> <p>10 central failure, is that he has only looked at</p> <p>11 those specimens which have come to him as a result</p> <p>12 of failures, of re-excision.</p> <p>13 He has not been able to look at the</p> <p>14 histopathology of all those 98 percent of the women</p> <p>15 who would have done well with their sling. And</p> <p>16 without looking that group, his conjectures about</p> <p>17 tissue compartmentalization and vascular this and</p> <p>18 edema that can't be substantiated because he has no</p> <p>19 comparative group.</p> <p>20 BY MR. RESTAINO:</p> <p>21 Q. In your opinion, is there any</p> <p>22 diagnostic modality that would allow a pathologist</p> <p>23 to look for that presence or absence of pathology</p> <p>24 in a living female who is not willing to undergo</p> <p>25 surgical procedure just for the purpose of study?</p> | <p style="text-align: right;">Page 165</p> <p>1 REPORTER'S CERTIFICATE</p> <p>2</p> <p>3 I, BONNIE LYNN VAN DER MEER, CSR,</p> <p>4 Certified Shorthand Reporter, certify;</p> <p>5 That the foregoing proceedings were</p> <p>6 taken before me at the time and place therein set</p> <p>7 forth, at which time the witness was put under oath</p> <p>8 by me;</p> <p>9 That the testimony of the witness</p> <p>10 and all objections made at the time of the</p> <p>11 examination were recorded stenographically by me</p> <p>12 and were thereafter transcribed;</p> <p>13 That the foregoing is a true and</p> <p>14 correct transcript of my shorthand notes so taken.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20 BONNIE LYNN VAN DER MEER, CSR</p> <p>21 REAL-TIME REPORTER</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |